NDA 16-979/S-049

Bristol-Myers Squibb Company
P.O. Box 4000
Princeton, NJ 08543-4000

JAN 31 2001

Attention: Joseph A. Linkewich, Pharm.D.
Director, Regulatory Science

Dear Mr. Linkewich:

Please refer to your supplemental new drug application dated April 6, 2000, received April 10, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Megace (megestrol acetate tablets, USP).

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert in compliance with Federal Register notices dated April 13 and November 16, 1999.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling submitted April 6, 2000. Accordingly, the supplemental application is approved effective on the date of this letter. However, we request that you make the following revisions at the next printing and report them in your next annual report:

1. Please revise the recommended storage conditions in the **HOW SUPPLIED** section, **Storage** subsection as follows:

   "Store at 25° C (77° F); excursions permitted to 15° - 30° C (59° - 86° F)[see USP Controlled Room Temperature]. Protect from temperatures above 40° C (104° F)."

2. All references and notations for references throughout the package insert should be removed.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under

21 CFR 314.80 and 314.81.

If you have any questions, call Christy Wilson, Consumer Safety Officer, at (301) 594-5761.

Sincerely,

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research